

K022520 page 1 of 2



U2 Acetabular Cup and Femoral Head

Summary

510(k) Summary of Safety and Effectiveness

Submitted By: United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park, Hsinchu, 300, Taiwan
Tel: 886-3-5773351
Fax: 886-3-5777156

Date July 24th, 2002

Contact person Jiann-Jong Liao / Regulatory Affairs

Device Name: U2 Acetabular Cup and Femoral head

Common Name: Acetabular Cup and Femoral head

Classification Name and Reference: 21CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Predicate Device: UNITED U1 Hip Prosthesis (K994078)

Device Description:

The U2 Acetabular Cup and Femoral Head are designated as an acetabular component and femoral head and are to be used with United U1 hip stem (K994078) and U2 hip stem (K003237) of total hip replacement. It is a modular type of product system. The U2 Acetabular Cup has ten sizes of options, hemispherical design, porous-coated surface on the metallic shell, clustered bone screw holes, spherical screw holes for variable screw locking angle, PMMA cement plug, easy snap-in and take out mechanism, 12 options for angle adjustment, minimum 6.9 mm thickness of UHMWPE liner. The metallic shell is produced from cast Co-Cr-Mo alloy (ASTM F75). The plastic liner is machined from extruded UHMWPE bars (ISO 5834/1). The U2 28 mm femoral head is aimed to providing more choice for orthopaedic surgeon to perform total hip arthroplasty. The taper angle of 28 mm femoral head is identical with U1 26 mm femoral head (K994078). Therefore, U2 28 mm femoral head can be used with our U1 and U2 hip stems. The U2 28 mm femoral head is available in -3, +0, +5, and +10 mm of neck length.

K&A 2520 page 2 of 2



U2 Acetabular Cup and Femoral Head

Summary

Intended Use:

The U2 Acetabular Cup and Femoral Head are indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
3. Correction of function deformity;
4. Revision procedures where other treatments or devices have failed; and
5. Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Basis for Substantial Equivalence:

Features comparable to predicate device, UNITED U1 hip prosthesis, include Co-Cr-Mo alloy substrate, beaded porous coated surface on the acetabular cup and 26 mm femoral head.

Test Results:

The static tensile and shear strength of the beaded porous coating are 27 MPa and 67 MPa respectively. The porosity of the porous coating ranges from 30 to 70 percent, the pore size ranges from 100 to 1000 microns and the thickness ranges from 500 to 1500 microns.

The range of motion of U2 Acetabular Cup is substantial equivalent to U1 Hip System (K994078).

Three biomechanical tests were performed, including push-out, lever-out and torque-out tests, to evaluate the locking mechanism of modular acetabular component. All test results are compared with U1 Hip System (K994078). The test results demonstrate that the integrity of locking mechanism between UHMWPE liner and metal acetabular shell of U2 Acetabular Cup is substantial equivalent to that of the predicate device.

Based on the previous test results, the U2 Acetabular Cup and Femoral head is substantial equivalent to UNITED U1 Hip system.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2003

Jiann-Jong Liao, Ph.D.
Regulatory Affairs
United Orthopedic Corporation
No. 57, Park Avenue 2, Science Park
Hsinchu, 300, Taiwan

Re: K022520

Trade/Device Name: U2 Acetabular Cup and Femoral Head

Regulation Numbers: 21 CFR 888.3358

Regulation Names: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: II

Product Code: LPH

Dated: November 24, 2002

Received: November 27, 2002

Dear Dr. Liao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

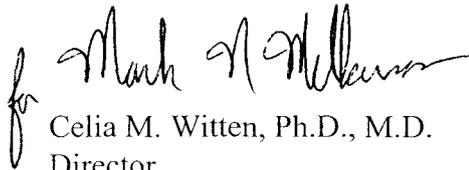
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a small "for" written to the left of the main name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K022520

Device Name: U2 Acetabular Cup and Femoral head

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Correction of function deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

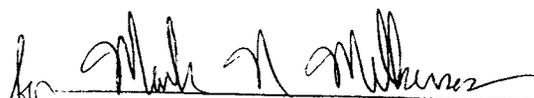
PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-The Counter Use _____


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022520